



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/961,086 | 09/21/2001 | Douglas D. Ross | 028754-039 | 6592 |

21839 7590 01/02/2004

BURNS DOANE SWECKER & MATHIS L L P
POST OFFICE BOX 1404
ALEXANDRIA, VA 22313-1404

| |
|----------|
| EXAMINER |
|----------|

UNGAR, SUSAN NMN

| | |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1642

DATE MAILED: 01/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|------------------------------------|--|
| Office Action Summary | Application No. 09/961,086 | Applicant(s) ROSS ET AL. | |
| | Examiner Susan Ungar | Art Unit 1642 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 21 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 5-7, 12-15, 18 and 21-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) 5-7, 12-15, 18, 21-37 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit:1642

1. Claims 5-7, 12-15, 18 and 21-37 are pending in the application and are currently under prosecution.

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Anthony Caputa, Ph.D., Supervisory Patent Examiner at 703-308-3995. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

Group 1. Claims 5-7 drawn to antibody to BCRP, classified in Class 530, subclasses 387.1 and 389.1.

3. Claim 12 link(s) inventions 2 and 3. The restriction requirement among/between the linked inventions is subject to the nonallowance of the linking claim(s), claim 12. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the

Art Unit:1642

claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Group 2. Claims 12, 23, 24 are drawn to a method of determining whether a patient is resistant to cancer chemotherapy drugs by assessing expression of a BCRP -7 with a monoclonal antibody against BCRP, classified in Class 435, subclass 7.1.

Group 3. Claims 12, 23, 25 are drawn to a method of determining whether a patient is resistant to cancer chemotherapy drugs by assessing expression of a BCRP -7 with a polyclonal antibody against BCRP, classified in Class 435, subclass 7.1.

4. Claims 13, 18, 29 link(s) inventions 4-9. The restriction requirement among/between the linked inventions is subject to the nonallowance of the linking claim(s), claims 13, 18 and 29. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application.

Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*,

Art Unit:1642

44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Group 4. Claims 13, 14, 18, 21 and 29, 36, 37 as drawn to monoclonal antibody to BCRP, are drawn to a method of enhancing chemotherapy/inhibiting the activity of BCRP in a patient's cell by administering monoclonal antibody against BCRP, classified in Class 424, subclass 130.1.

Group 5. Claims 13, 15, 18, 22 and 29, 36, 37 as drawn to polyclonal antibody to BCRP, are drawn to a method of enhancing chemotherapy/inhibiting the activity of BCRP in a patient's cell by administering polyclonal antibody against BCRP, classified in Class 424, subclass 130.1.

Group 6. Claims 29, 36, 37 is drawn to a method of enhancing chemotherapy/inhibiting the activity of BCRP in a patient's cell by administering a compound, BBR3390, that inhibits activity of BCRP, classified in Class 514, subclass 2+.

Group 7. Claims 29, 36, 37 is drawn to a method of enhancing chemotherapy/inhibiting the activity of BCRP in a patient's cell by administering a compound, antisense RNA to BCRP, that inhibits activity of BCRP, classified in Class 514, subclass 44.

Group 8. Claims 29, 36, 37 is drawn to a method of enhancing chemotherapy/inhibiting the activity of BCRP in a patient's cell by administering a compound, Fumitremorgin C, that inhibits activity of BCRP, classified in Class 514, subclass 2+.

Art Unit:1642

Group 9. Claim 29 and 30 are drawn to a method of enhancing chemotherapy/inhibiting the activity of BCRP in a patient's cell by administering two compounds that inhibit activity of BCRP, classified in Class 424, subclass 130.1 and Class 514, subclass 2+.

5. Claim 31 link(s) inventions 10-15/((A)-(E). The restriction requirement among/between the linked inventions is subject to the nonallowance of the linking claim(s), claims 31. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Group 10. Claims 31-35 are drawn to a method for identifying a compound that inhibits BCRP comprising exposing MCF-7/AdrVp cells which express BCRP to an agent transported by BCRP in the presence of said compound, classified in Class 435, subclass 4.

Group 11. Claims 31-35 are drawn to a method for identifying a compound that inhibits BCRP comprising exposing colon carcinoma S1 cells

Art Unit:1642

which express BCRP to an agent transported by BCRP in the presence of said compound, classified in Class 435, subclass 4.

Group 12. Claims 31-35 are drawn to a method for identifying a compound that inhibits BCRP comprising exposing HT29 cells which express BCRP to an agent transported by BCRP in the presence of said compound, classified in Class 435, subclass 4.

Group 13. Claims 31-35 are drawn to a method for identifying a compound that inhibits BCRP comprising exposing gastric carcinoma EPG85-257 cells which express BCRP to an agent transported by BCRP in the presence of said compound, classified in Class 435, subclass 4.

Group 14. Claims 31-35 are drawn to a method for identifying a compound that inhibits BCRP comprising exposing fibrosarcoma EPR86-079 cells which express BCRP to an agent transported by BCRP in the presence of said compound, classified in Class 435, subclass 4.

Group 15. Claims 31-35 are drawn to a method for identifying a compound that inhibits BCRP comprising exposing myeloma 8226 cells which express BCRP to an agent transported by BCRP in the presence of said compound, classified in Class 435, subclass 4.

For each of the inventions 10-15 above, restriction to one of the following is also required under 35 USC 121. Therefore, election is required of one of inventions 10-15 and one of inventions (A)-(C). It is noted that this is not an election of species requirement in that each of the linked groups consists of one of inventions 10-15 above and one of inventions (A)-(C) as claimed, and (D)-(E) as disclosed, below.

(A) mitoxantrone

Art Unit:1642

- (B) daunorubicin
- (C) doxorubicin
- (D) monoclonal antibody against BCRP
- (E) polyclonal antibody against BCRP

Group 16. Claims 26-28 are drawn to of determining the cause of a cell's resistance to cancer chemotherapy drugs, classified in Class 435 subclass 4.

6. The inventions are distinct, each from the other because of the following reasons:

Inventions 2-16 are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success.

The inventions of Groups 1 and 2-5/9-16 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (I) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § **806.05(h)**]. In the instant case the antibody products as claimed and disclosed can be used in a materially different process such as producing anti-idiotypic antibodies.

The inventions of groups 1 and 6-8 are not at all related because the antibodies of Group 1 are not used in the methods of groups 6-8.

7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Art Unit:1642

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R.

§ 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

10. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (703) 305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

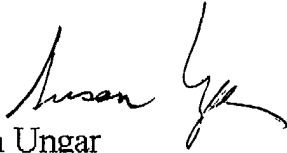
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached at (703) 308-3995. The fax phone number for this Art Unit is (703) 308-4242.

Serial No: 09/961,086

Page 8

Art Unit:1642

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

A handwritten signature in black ink, appearing to read "Susan Ungar", with a stylized flourish at the end.

Susan Ungar
Primary Patent Examiner
December 17, 2003